

REMARKS

Claims 1-4 were examined and acted upon in the aforesaid Office Action. No claim has been canceled and no new claim has been added, leaving claims 1-4 for further consideration.

Claims 1 and 4 were rejected under 35 USC 103 as being unpatentable over Middleman et al. (believed to be WO91/02493) in view of Yoon (believed to be USP 5,226,426).

The patent to Middleman discloses an arthroscopic and/or laparoscopic device having grasping elements. More particularly, Middleman discloses a grasping device with two opposing pseudoelastic grasping elements 1 and 3, each made of shape memory alloys, which are pinned together at their distal ends and are movably disposed within the constraint of an elongate housing 11 in the form of a hollow tube. In another form of the invention (Fig. 9), the grasping elements 102, 106 are flat ribbon-like elements which include inwardly bent tips 104, 105 which remain separated with a relatively large opening therebetween when within the cannula 10 (see lower or left portion of Fig. 9). Accordingly to the teaching of Middleman, when the pseudoelastic grasping elements are pushed outward from the constraining tube, they diverge or splay outwardly from one another in an exaggerated and wide posture as clearly shown in

Fig. 9 (designated as the 501 position). In this wider splayed position, large objects, such as pieces of tissue, may be positioned between the grasping elements and, thereafter, grasped as the elements 102, 106 are brought toward one another (see Fig. 9, designated as the 502 position).

Middleman fails to provide any suggestion or teaching of providing grasping elements that are capable of retaining and/or grappling a thin cord-like object, such as a suture. The nature of applicant's wire-like elements is clearly set forth in claims 1 and 4. The first wire-like element has a hook-shape 85 at its distal end, and the second wire-like element defines a guide means at its distal end. As the wire-like elements are positioned around a suture and then retracted into their first position, the guide means of the second wire-like element urges the suture into engagement with the hook of the first wire-like element, whereby the thin suture can be captured to the shaft 10. It is this construction which permits the easy grasping and retaining of sutures. Such structure is recited in Applicant's claims 1 and 4 and is not suggested or taught by Middleman.

Claims 1 and 4 have been extensively amended to further define the hook shape nature of the second wire-like element distal end portion and its relationship to the first wire-like

element distal end portion, such that one distal segment extends substantially normal to the other distal segment when the wire-like elements are disposed in their extended positions. This arrangement does not appear to be present in Middleman, Yoon, Knoepfler and Hasson.

Applicant respectfully submits that the grasping elements 102, 106 in Middleman, including the opposing bent tips 104, 105, are incapable of retaining and/or grappling an object such as a suture. As illustrated in Fig. 9 of Middleman, each inwardly bent tip 104, 105 is generally shown to be substantially at a right or an obtuse angle relative to the remaining portion of its corresponding element 102, 106. When the grasping elements 102, 106 are moved into a fully splayed position, the portion immediately adjacent to each bent tip lies substantially parallel to the surface of the object to be grasped (see position designation 501). Such deployment of the elements 102, 106 renders them incapable of grasping a thin structure.

If an object, such as a thin suture, were attempted to be grasped by the Middleman device, such suture must be oriented in a position extending axially of the grasping elements 102, 106 and normal to the end portions 104, 105. Thus, grasping the suture is difficult, if not impossible, with the Middleman

device. Even then, the Middleman grasping elements 102, 106 would appear unable to provide the tips 104, 105 with sufficient contact against the suture to enable grasping it. Accordingly, when the elements are brought toward one another, the tips cannot securely grip and pull the suspending suture upward between the elements. The suture consequently cannot be retained and may slip away from between the tips 104, 105. This is especially so because the bends 104, 105 are at a substantially right angle, and the material of the elements 102, 106 cause them to remain slightly splayed apart even when within the cannula 103 (see lefthand view of Fig. 9). In this splayed position, there exists a relatively large space between the two elements at the area immediately adjacent the bent tips 104, 105. The presence of such a space prevents an object smaller than the space, such as a suture, from being grasped and retained by the elements 102, 106, and will allow the small object to slip out.

Although Yoon does show the use of a "sharp, tissue penetrating tip" 46 on a cylindrical needle 32, the grasping end of a safety probe 34 which slides within the needle 32 is a split or slotted distal end forming generally large blunt linear grasping elements 132 and 134. Such elements certainly are not wire-like, as required by the claims herein. The intention with

Yoon, as with Middleman, is to grasp and/or cut tissue and not to grasp and retain a thin object, such as a suture. Similar to Middleman, when the linear elements 132, 134 of Yoon are fully biased outwardly they cannot sufficiently contact a suspended suture so as to pull the suture upward between the elements.

Combining the teaching of Yoon with Middleman to place a sharp tip on hollow shaft 11 of Middleman still does not render the claimed invention obvious. Neither Middleman nor Yoon employ wire-like elements to slide within a shaft, one of the elements having a "hook-shape", and the elements being so arranged that when withdrawn into the shaft the suture will be captured to the shaft. Accordingly, it is submitted that the rejection of claims 1 and 4 over the combination of Yoon with Middleman is untenable since the combined references still fail to render the claimed invention obvious, for the reasons discussed above.

Claim 2 has been rejected under 35 USC 103 as being unpatentable over Middleman in view of Yoon as applied to claim 1, and further in view of Knoepfler (USP 5,209,747).

The patent to Knoepfler teaches an adjustable angle medical forceps. In particular, Knoepfler discloses a medical forceps 1 having a first tubular housing 11 and, at a distal portion thereof, a second tubular housing 30 which is rotatable with

respect to the first housing. Two jaw elements 34, 35 divergently extend from within the second housing. The jaw elements are constructed so that they can be brought together to grasp an object. The forceps, adapted for use during laparoscopic surgery, must be inserted through a slender, cylindrical cannula to access an area within the body. To traverse the cannula, the rotated second housing 30 must be brought into straight alignment with the first housing. Knoepfler specifically discourages (see column 1, lines 30 to 47) the use of fixed angle forceps since they are not able to traverse a slender cylindrical cannula. Knoepfler does not disclose a "substantially rigid shaft having a distal end" which is curved, as recited in Applicant's claim 2.

The grasping device of the present invention as set forth in claim 2, is characterized by a rigidly fixed curved distal end which is not anticipated by the articular multiple tube shafts of Knoepfler. In addition, since the parent claim 1 should not be deemed obvious by the combination of Yoon with Middleman for the reasons given above, the addition of an articular arm to the shaft 11 of Middleman does not result in a device which renders obvious the device of dependent claim 2.

Claim 3 has been rejected under 35 USC section 103 as being unpatentable over Middleman in view of Yoon as applied to claim 1, and further in view of Hasson.

The failure of the combination of Middleman and Yoon to provide a supportable basis for obviousness for parent claim 1 has been discussed above and is applicable to the rejection of dependent claim 3.

Claim 3 further recites that Applicant's activation means including a spring biasing means comprising spring 110 which normally urges rod 12 into the position where the wire-like members 15 and 20 are contained within shaft 10. In the Hasson instrument spring means 44 normally urges the stem 12 rearwardly, as viewed in Figs. 1 and 4, to cause forceps arm 18 to come together into a clustered-together position, but the arms 18 are not withdrawn into the tubular sleeve 26 (see Fig. 1). Thus, at no time are the arms 18 of Hasson contained within his sleeve 26, as required by parent claim 1, and hence by dependent claim 3. It is, therefore, submitted that combining the teaching of Hasson with that of Middleman and Yoon still does not arrive at the device claimed in claim 3.

In short, the various features of construction of the distal end segments of the wire-like elements appear not to be shown or

suggested by the art cited, taken singly or in combination. These features enable the device of the invention to grasp and securely retain a suture which will not slip out from the tube, even if the device makes a sudden lateral and/or vertical movement relative to the suture.

In view of the foregoing, and for the reasons discussed above in connection with each rejection, it is respectfully submitted that claims 1-4, inclusive, presently pending in the application are allowable over the art cited. Reconsideration of the application is therefore respectfully requested and a favorable action solicited.



In the event that any additional fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott R. Foster". The signature is fluid and cursive, with the first name "Scott" and last name "Foster" clearly distinguishable.

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